

ATTACHMENT 6

Traditional 510(k) Notification



Re-manufactured EndoWrists

Rebotix, LLC
Saint Petersburg, FL

Exhibit
DX 255

Module (A) Administration**Table of Contents**

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Notes on organization:

This submission has been organized into eleven (11) self-contained modules that mirror the organization of FDA's RTA checklist. Page numbers and attachments within a given module are prefixed with the letter of that module (e.g. "Attachment E-2"). The ultimate goal is to apply a logical and intuitive organization structure that will facilitate an efficient review. Bookmarks have also been implemented in order to aid navigation within each module.



445 Apollo Beach Blvd, Apollo Beach, FL 33572
Phone: (813) 645-2855
FAX: (813) 645-2856

Date: December 18, 2014

Document Mail Center (W066-06)
Center For Devices and Radiological Health
Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993

Re: Traditional 510(k) Submission

Dear Madam or Sir:

In accordance with Title 21 CFR 807.81, we are notifying you of our client's intent to manufacture, package, and put into commercial distribution:

Trade Name: Re-manufactured EndoWrist
Common Name: Endoscopic instrument control system, endoscopic instruments and accessories
Class: II
Panel: General & Plastic Surgery

Enclosed is one paper copy of the original submission. Per the instructions accessed at <http://www.fda.gov/cdrh/elecsub.html>, an electronic copy is being provided with this submission and it is an exact duplicate of the original paper submission. There have been no prior submissions for the Re-manufactured EndoWrist which FDA determined were NSE, were deleted or withdrawn.

If you need any additional information, please contact the writer.

Sincerely,

A handwritten signature in blue ink that reads "Ryan Burke".

Ryan Burke

List of Attachments

Medical Device User Fee Cover Sheet	Attachment A-1
CDRH Premarket Review Cover Sheet (Form 3514)	Attachment A-2
Additional Model Numbers (Form 3514)	Attachment A-3
Indications for Use	Attachment A-4
510(k) Summary	Attachment A-5
Truthful and Accuracy Statement	Attachment A-6
Standards Data Report (Form 3654)	Attachment A-7

Attachment A-1 – Medical Device User Fee Coversheet

Form Approved: OMB No. 0910-0511 Expiration Date: April 30, 2016. See Instructions for OMB Statement.

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION MEDICAL DEVICE USER FEE COVER SHEET		PAYMENT IDENTIFICATION NUMBER: MD6079161 Write the Payment Identification number on your check.
<p>A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: http://www.fda.gov/oc/dufma/coversheet.html</p>		
1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)	2. CONTACT NAME Joe Morrisson 2.1 E-MAIL ADDRESS usagent@ajwtech.com 2.2 TELEPHONE NUMBER (include Area code) 727-3434914 2.3 FACSIMILE (FAX) NUMBER (Include Area code)	
1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) *****1329		
3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm345263.htm		
<u>Select an application type:</u>		
<input checked="" type="checkbox"/> Premarket notification(510(k)); except for third party <input type="checkbox"/> 513(g) Request for Information <input type="checkbox"/> Biologics License Application (BLA) <input type="checkbox"/> Premarket Approval Application (PMA) <input type="checkbox"/> Modular PMA <input type="checkbox"/> Product Development Protocol (PDP) <input type="checkbox"/> Premarket Report (PMR) <input type="checkbox"/> 30-Day Notice		
<u>3.1 Select a center</u> <input checked="" type="checkbox"/> CDRH <input type="checkbox"/> CBER		
<u>3.2 Select one of the types below</u> <input checked="" type="checkbox"/> Original Application <u>Supplement Types:</u> <input type="checkbox"/> Efficacy (BLA) <input type="checkbox"/> Panel Track (PMA, PMR, PDP) <input type="checkbox"/> Real-Time (PMA, PMR, PDP) <input type="checkbox"/> 180-day (PMA, PMR, PDP)		
4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status)		
<input type="checkbox"/> YES, I meet the small business criteria and have submitted <input checked="" type="checkbox"/> NO, I am not a small business the required qualifying documents to FDA		
4.1 If Yes, please enter your Small Business Decision Number:		
5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA?		
<input checked="" type="checkbox"/> YES (All of our establishments have registered and paid the fee, or this is our first device, and we will register and pay the fee within 30 days of FDA's approval/clearance of this device.) <input type="checkbox"/> NO (If "NO," FDA will not accept your submission until you have paid all fees due to FDA. This submission will not be processed; see http://www.fda.gov/cdrh/dufma for additional information)		
6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.		
<input type="checkbox"/> This application is the first PMA submitted by a qualified small business, including any affiliates <input type="checkbox"/> The sole purpose of the application is to support conditions of use for a pediatric population		

This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only

The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

7. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).)

YES

NO

PAPERWORK REDUCTION ACT STATEMENT

Public reporting burden for this collection of information is estimated to average 18 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the address below.

Department of Health and Human Services, Food and Drug Administration, Office of Chief Information Officer, 8455 Colesville Road, COLE-14-14253 Silver Spring, MD 20993-0002

[Please do NOT return this form to the above address, except as it pertains to comments on the burden estimate.]

8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION

\$5,018.00

15-Dec-
2014

Form FDA 3601 (01/2007)

["Close Window"](#) [Print Cover sheet](#)

Attachment A-2 – CDRH Premarket Review Cover Sheet

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION CDRH PREMARKET REVIEW SUBMISSION COVER SHEET				Form Approval OMB No. 0910-0120 Expiration Date: December 31, 2013 See PRA Statement on page 5.																																																																																																																						
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SECTION C <table border="1"> <thead> <tr> <th colspan="4">APPLICATION CORRESPONDENT (e.g., consultant, if different from above)</th> </tr> </thead> <tbody> <tr> <td colspan="2">Company / Institution Name AJW Technology Consultants, Inc</td> <td colspan="3"></td> </tr> <tr> <td colspan="2">Division Name (<i>if applicable</i>)</td> <td colspan="3">Phone Number (<i>including area code</i>) (813) 645-2855</td> </tr> <tr> <td colspan="2">Street Address 445 Apollo Beach Blvd</td> <td colspan="3">FAX Number (<i>including area code</i>) (813) 645-2856</td> </tr> <tr> <td colspan="2">City Apollo Beach</td> <td colspan="2">State / Province FL</td> <td>ZIP Code 33572</td> </tr> <tr> <td colspan="2">Contact Name Ryan Burke</td> <td colspan="3">Country USA</td> </tr> <tr> <td colspan="2">Contact Title Regulatory and Quality Consultant</td> <td colspan="3">Contact E-mail Address rburke@ajwtech.com</td> </tr> </tbody> </table>					APPLICATION CORRESPONDENT (e.g., consultant, if different from above)				Company / Institution Name AJW Technology Consultants, Inc					Division Name (<i>if applicable</i>)		Phone Number (<i>including area code</i>) (813) 645-2855			Street Address 445 Apollo Beach Blvd		FAX Number (<i>including area code</i>) (813) 645-2856			City Apollo Beach		State / Province FL		ZIP Code 33572	Contact Name Ryan Burke		Country USA			Contact Title Regulatory and Quality Consultant		Contact E-mail Address rburke@ajwtech.com																																																																																						
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REASON FOR APPLICATION - PMA, PDP, OR HDE		
<input type="checkbox"/> New Device <input type="checkbox"/> Withdrawal <input type="checkbox"/> Additional or Expanded Indications <input type="checkbox"/> Request for Extension <input type="checkbox"/> Post-approval Study Protocol <input type="checkbox"/> Request for Applicant Hold <input type="checkbox"/> Request for Removal of Applicant Hold <input type="checkbox"/> Request to Remove or Add Manufacturing Site	<input type="checkbox"/> Change in design, component, or specification: <input type="checkbox"/> Software / Hardware <input type="checkbox"/> Color Additive <input type="checkbox"/> Material <input type="checkbox"/> Specifications <input type="checkbox"/> Other (specify below)	<input type="checkbox"/> Location change: <input type="checkbox"/> Manufacturer <input type="checkbox"/> Sterilizer <input type="checkbox"/> Packager
<input type="checkbox"/> Process change: <input type="checkbox"/> Manufacturing <input type="checkbox"/> Packaging <input type="checkbox"/> Sterilization <input type="checkbox"/> Other (specify below)	<input type="checkbox"/> Labeling change: <input type="checkbox"/> Indications <input type="checkbox"/> Instructions <input type="checkbox"/> Performance Characteristics <input type="checkbox"/> Shelf Life <input type="checkbox"/> Trade Name <input type="checkbox"/> Other (specify below)	<input type="checkbox"/> Report Submission: <input type="checkbox"/> Annual or Periodic <input type="checkbox"/> Post-approval Study <input type="checkbox"/> Adverse Reaction <input type="checkbox"/> Device Defect <input type="checkbox"/> Amendment
<input type="checkbox"/> Response to FDA correspondence:		<input type="checkbox"/> Change in Ownership <input type="checkbox"/> Change in Correspondent <input type="checkbox"/> Change of Applicant Address
<input type="checkbox"/> Other Reason (specify):		
REASON FOR APPLICATION - IDE		
<input type="checkbox"/> New Device <input type="checkbox"/> New Indication <input type="checkbox"/> Addition of Institution <input type="checkbox"/> Expansion / Extension of Study <input type="checkbox"/> IRB Certification <input type="checkbox"/> Termination of Study <input type="checkbox"/> Withdrawal of Application <input type="checkbox"/> Unanticipated Adverse Effect <input type="checkbox"/> Notification of Emergency Use <input type="checkbox"/> Compassionate Use Request <input type="checkbox"/> Treatment IDE <input type="checkbox"/> Continued Access	<input type="checkbox"/> Change in: <input type="checkbox"/> Correspondent/Applicant <input type="checkbox"/> Design/Device <input type="checkbox"/> Informed Consent <input type="checkbox"/> Manufacturer <input type="checkbox"/> Manufacturing Process <input type="checkbox"/> Protocol - Feasibility <input type="checkbox"/> Protocol - Other <input type="checkbox"/> Sponsor	<input type="checkbox"/> Response to FDA Letter Concerning: <input type="checkbox"/> Conditional Approval <input type="checkbox"/> Deemed Approved <input type="checkbox"/> Deficient Final Report <input type="checkbox"/> Deficient Progress Report <input type="checkbox"/> Deficient Investigator Report <input type="checkbox"/> Disapproval <input type="checkbox"/> Request Extension of Time to Respond to FDA <input type="checkbox"/> Request Meeting <input type="checkbox"/> Request Hearing
<input type="checkbox"/> Other Reason (specify):		
REASON FOR SUBMISSION - 510(k)		
<input checked="" type="checkbox"/> New Device	<input type="checkbox"/> Additional or Expanded Indications	<input type="checkbox"/> Change in Technology
<input type="checkbox"/> Other Reason (specify):		

SECTION E

ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	NAY	2	3	4		Summary of, or statement concerning, safety and effectiveness information <input checked="" type="checkbox"/> 510 (k) summary attached <input type="checkbox"/> 510 (k) statement
5		6	7	8		

Information on devices to which substantial equivalence is claimed (if known)

	510(k) Number	Trade or Proprietary or Model Name	Manufacturer
1	K063220	1 DA VINCI S SURGICAL SYSTEM-V1.1, MODEL IS2000	1 INTUITIVE SURGICAL, INC.
2	K081137	2 INTUITIVE SURGICAL DA VINCI SI SURGICAL SYSTEM: MODEL IS3000	2 INTUITIVE SURGICAL, INC.
3		3	3
4		4	4
5		5	5
6		6	6

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification name

System, Surgical, Computer Controlled Instrument

	Trade or Proprietary or Model Name for This Device	Model Number
1	Potts Scissors	1 420001
2	Large Needle Driver	2 420006
3	Round Tip Scissors	3 420007
4	DeBakey Forceps	4 420036
5	Long Tip Forceps	5 420048

FDA document numbers of all prior related submissions (regardless of outcome)

1	2	3	4	5	6
7	8	9	10	11	12

Data Included in Submission

 Laboratory Testing Animal Trials Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code NAY	C.F.R. Section (if applicable) 876.1500	Device Class <input type="checkbox"/> Class I <input checked="" type="checkbox"/> Class II <input type="checkbox"/> Class III <input type="checkbox"/> Unclassified
Classification Panel General & Plastic Surgery		

Indications (from labeling)

EndoWrist® Instruments, including scissors, scalpels, forceps, needle drivers and electrocautery are intended for endoscopic manipulation of tissue, including: grasping, cutting, blunt and sharp dissection, approximation, ligation, electrocautery and suturing.

The Instrument is for use only with the Intuitive da Vinci® S and da Vinci® Si Systems (Endoscopic Instrument Control System).

SECTION H		MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION			
<input checked="" type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete		Facility Establishment Identifier (FEI) Number		<input checked="" type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Contract Manufacturer <input type="checkbox"/> Repackager / Relabeler	
Company / Institution Name Rebotix, LLC		Establishment Registration Number			
Division Name (if applicable)		Phone Number (including area code) 727-343-4914			
Street Address 539 Pasadena Avenue South		FAX Number (including area code)			
City St. Petersburg		State / Province FL	ZIP Code 33707	Country USA	
Contact Name Joe Morrison		Contact Title Operations Manager	Contact E-mail Address joemorrison@rebotix.net		
<input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete		Facility Establishment Identifier (FEI) Number		<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Contract Manufacturer <input type="checkbox"/> Repackager / Relabeler	
Company / Institution Name		Establishment Registration Number			
Division Name (if applicable)		Phone Number (including area code)			
Street Address		FAX Number (including area code)			
City		State / Province	ZIP Code	Country	
Contact Name		Contact Title	Contact E-mail Address		
<input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete		Facility Establishment Identifier (FEI) Number		<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Contract Manufacturer <input type="checkbox"/> Repackager / Relabeler	
Company / Institution Name		Establishment Registration Number			
Division Name (if applicable)		Phone Number (including area code)			
Street Address		FAX Number (including area code)			
City		State / Province	ZIP Code	Country	
Contact Name		Contact Title	Contact E-mail Address		

Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.

FDA Document Number (*if known*)**SECTION H (Continued)**

<input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	Facility Establishment Identifier (FEI) Number	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Manufacturer	<input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Repackager / Relabeler
Company / Institution Name		Establishment Registration Number	
Division Name (<i>if applicable</i>)		Phone Number (<i>including area code</i>)	
Street Address		FAX Number (<i>including area code</i>)	
City		State / Province	ZIP Code
Contact Name		Contact Title	Contact E-mail Address
<input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	Facility Establishment Identifier (FEI) Number	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Manufacturer	<input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Repackager / Relabeler
Company / Institution Name		Establishment Registration Number	
Division Name (<i>if applicable</i>)		Phone Number (<i>including area code</i>)	
Street Address		FAX Number (<i>including area code</i>)	
City		State / Province	ZIP Code
Contact Name		Contact Title	Contact E-mail Address
<input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	Facility Establishment Identifier (FEI) Number	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Manufacturer	<input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Repackager / Relabeler
Company / Institution Name		Establishment Registration Number	
Division Name (<i>if applicable</i>)		Phone Number (<i>including area code</i>)	
Street Address		FAX Number (<i>including area code</i>)	
City		State / Province	ZIP Code
Contact Name		Contact Title	Contact E-mail Address

SECTION I

UTILIZATION OF STANDARDS

Note: Complete this section if your application or submission cites standards or includes a "Declaration of Conformity to a Recognized Standard" statement.

1	Standards No. 60601-1	Standards Organization AAMI ANSI	Standards Title Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance	Version Third Edition 2012	Date
2	Standards No. 60601-1-2	Standards Organization IEC	Standards Title Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements And Tests	Version Third Edition 2007	Date
3	Standards No. 60601-2-2	Standards Organization IEC	Standards Title Medical Electrical Equipment - Part 2-2: Particular Requirements For The Basic Safety And Essential Performance Of High Frequency Surgical Equipment And High Frequency Surgical Accessories	Version Fifth Edition 2009	Date
4	Standards No. 10993-1	Standards Organization ISO	Standards Title Biological Evaluation Of Medical Devices - Part 1: Evaluation And Testing Within A Risk Management Process	Version Fourth Edition 2009-10-15	Date
5	Standards No. 10993-5	Standards Organization AAMI ANSI ISO	Standards Title Biological Evaluation Of Medical Devices -- Part 5: Tests For In Vitro Cytotoxicity	Version 2009/(R) 2014	Date
6	Standards No. 10993-10	Standards Organization ISO	Standards Title Biological Evaluation Of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization	Version Third Edition 2010-08-01	Date
7	Standards No. 10993-11	Standards Organization ISO	Standards Title Biological Evaluation Of Medical Devices Part 11: Tests For Systemic Toxicity	Version Second Edition 2006-08-15	Date

Please include any additional standards to be cited on a separate page.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF ADDRESS BELOW.

The burden time for this collection of information is estimated to average 0.5 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
1350 Piccard Drive, Room 400
Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Attachment A-3 Addendum to FDA Form 3514

Addendum to Form FDA 3514

Table A-1 Model Numbers continued from Section F:

#	Trade or Proprietary or Model Name for This Device	Model Number
6	Cadiere Forceps	420049
7	ProGrasp™ Forceps	420093
8	PreCise™ Bipolar Forceps	420110
9	Micro Bipolar Forceps	420171
10	Maryland Bipolar Forceps	420172
11	Curved Scissors	420178
12	Hot Shears™ (Monopolar Curved Scissors)	420179
13	Resano Forceps	420181
14	Permanent Cautery Hook	420183
15	Permanent Cautery Spatula	420184
16	Double Fenestrated Grasper	420189
17	Cobra Grasper	420190
18	Mega™ Needle Driver	420194
19	Fenestrated Bipolar Forceps	420205
20	Tenaculum Forceps	420207
21	PK® Dissecting Forceps	420227
22	Large SutureCut™ Needle Driver	420296
23	Mega SutureCut™ Needle Driver	420309
24	Curved Bipolar Dissector	420344

Table A-2 Standards Utilized Continued from Section I

Standards No.	Standards Organization	Standards Title	Version
10993-4	ISO	Biological evaluation of medical devices -- Part 4: Selection of tests for interactions with blood	2002
F756-13	ASTM	Standard Practice For Assessment Of Hemolytic Properties Of Materials. (Biocompatibility)	2013

Attachment A-4 – Indications For Use

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number (if known)

Device Name
Re-manufactured EndoWrists

Indications for Use (Describe)

EndoWrist® Instruments, including scissors, scalpels, forceps, needle drivers and electrocautery are intended for endoscopic manipulation of tissue, including: grasping, cutting, blunt and sharp dissection, approximation, ligation, electrocautery and suturing.

The Instrument is for use only with the Intuitive da Vinci® S and da Vinci® Si Systems (Endoscopic Instrument Control System).

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D) Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Attachment A-5 – 510(k) Summary

**510(k) SUMMARY
(as required by 807.92)**

I. SUBMITTER

Rebotix, LLC
539 Pasadena Ave. S.
Saint Petersburg, FL 33707

Phone: 727-343-4914

Contact Person: Joe Morrison
Date Prepared: 12/18/2014

REGULATORY CORRESPONDENT

AJW Technology Consultants, Inc
445 Apollo Beach, Blvd
Apollo Beach, FL 33572

Phone: 813-645-2855
Fax: 813-645-2856

Contact Person: Ryan Burke
Email: rburke@ajwtech.com

II. DEVICE

Name of Device: Re-manufactured EndoWrists
Common or Usual Name/
Classification Name: Endoscopic instrument control system, endoscopic instruments and accessories
Device Panel: General & Plastic Surgery
Regulatory Class: Class II
Product Code: NAY

III. PREDICATE DEVICE

The Re-manufactured EndoWrists are substantially equivalent in intended use and similar technological characteristics of the Intuitive Surgical Endoscopic Instrument Control System (Model IS2000) and EndoWrist Endoscopic Instruments as part of K063220, and the Intuitive Surgical, Inc. da Vinci Si Surgical System (Model IS3000) which was cleared under K081137.

These predicates have not been subject to a design-related recall.
No reference devices were used in this submission

IV. DEVICE DESCRIPTION

The Re-Manufactured EndoWrists are multiple-use endoscopic instruments to be used in conjunction with the Intuitive Surgical Endoscopic Instrument Control System. The subject device(s) consist of a family of endoscopic instruments with either grasping or cutting end effectors to be used with the Intuitive Surgical da Vinci Endoscopic Instrument Control System. These instruments attach to the instrument manipulator arms on the Intuitive Surgical Endoscopic Instrument Control System. The instruments are re-usable (for a limited number of uses), are provided non-sterile, and must be cleaned and sterilized before used (pre-vacuum autoclave). The instruments are programmed for a limited number of uses to ensure reliability and consistent performance.

The instruments attach to disposable, sterile adaptor on the manipulator arm of the Endoscopic Instrument Control System to provide a barrier between the (sterile) instrument and the (non-sterile) manipulator arm. This allows instruments to be interchangeable during a procedure, without compromising the sterile barrier. When attached to the manipulator, the instrument is inserted through a cannula mounted to the manipulator.

All instruments have articulations at the distal end that are controlled by the surgeon. The instrument is the “wrist” of the system and provides four (4) degrees of freedom (wrist pitch, wrist yaw, rotation and grip). These instruments share similar architecture, materials, and manufacturing processes. The primary difference between the instruments is the tip end effector also known as the “tool end”.

V. INDICATIONS FOR USE

EndoWrist® Instruments, including scissors, scalpels, forceps, needle drivers and electrocautery are intended for endoscopic manipulation of tissue, including: grasping, cutting, blunt and sharp dissection, approximation, ligation, electrocautery and suturing.

The Instrument is for use only with the Intuitive da Vinci® S and da Vinci® Si Systems (Endoscopic Instrument Control System).

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The minor modifications that are made to the EndoWrists during the re-manufacturing process serve only to restore them to OEM-equivalent performance specifications, and therefore do not represent changes to the technological characteristics of the devices.

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination:

Biocompatibility Testing

The product contact materials utilized in the Re-manufactured EndoWrists have been well characterized chemically and physically and have a long history of safe use in predicate devices. In addition, all patient contact components have been FDA cleared through the 510(k) Premarket Notification process and have been tested for biocompatibility.

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the Re-manufactured EndoWrists devices. The devices continue to comply with the IEC 60601-1 standards for safety and the IEC 60601-1-2 standard for EMC.

Software Verification and Validation Testing

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "Moderate" level of concern, since a failure or latent flaw could directly result in minor injury to the patient or operator.

VIII. CONCLUSIONS

The testing completed demonstrates that the Re-manufactured EndoWrists exhibits comparable technical and functional characteristics to the predicate devices. Based on those characteristics, the Re-manufactured EndoWrists are substantially equivalent to the predicate device in safety and effectiveness in addition to having the same intended use.

Attachment A-6 – Truthful and Accuracy Statement

PREMARKET NOTIFICATION

TRUTHFUL AND ACCURATE STATEMENT

(As Required By 21 CFR 807.87(k))

I certify that, in my capacity as Managing Member of *Rebotix, LLC*, I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.



Signature

David B. Mixner
Name (Print or Type)

12/18/14

Date

Premarket Notification 510(k)

Attachment A-7 – Standards Data Report Form (3654)

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s
(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE ¹

AAMI ANSI ES60601-1:2005/(R)2012 And A1:2012 Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance

Please answer the following questions

Yes No

Is this standard recognized by FDA ² ?

FDA Recognition number³ #19-4

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?

Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)?

If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?

Does this standard include acceptance criteria?

If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests?

If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard?

If yes, were deviations in accordance with the FDA supplemental information sheet (SIS)⁵?

Were deviations or adaptations made beyond what is specified in the FDA SIS?

If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard?

If yes, report these exclusions in the summary report table.

Is there an FDA guidance ⁶ that is associated with this standard?

If yes, was the guidance document followed in preparation of this 510k?

Title of guidance: _____

¹ The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

² Authority [21 U.S.C. 360d], <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm>

⁵ The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

³ <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

⁶ The online search for CDRH Guidance Documents can be found at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>

**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE

AAMI ANSI ES60601-1:2005/(R)2012 And A1:2012 Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED [◊]

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED [◊]

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED [◊]

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

◊ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 1 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
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Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

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Department of Health and Human Services

Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

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TYPE OF 510(K) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE ¹

IEC 60601-1-2 Edition 3: 2007-03 Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements And Tests

Please answer the following questions

Yes No

Is this standard recognized by FDA ² ?

FDA Recognition number³ #19-1

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?

Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)?

If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?

Does this standard include acceptance criteria?

If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests?

If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard?

If yes, were deviations in accordance with the FDA supplemental information sheet (SIS)⁵?

Were deviations or adaptations made beyond what is specified in the FDA SIS?

If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard?

If yes, report these exclusions in the summary report table.

Is there an FDA guidance ⁶ that is associated with this standard?

If yes, was the guidance document followed in preparation of this 510k?

Title of guidance: _____

¹ The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

² Authority [21 U.S.C. 360d], <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm>

⁵ The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

³ <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

⁶ The online search for CDRH Guidance Documents can be found at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>

**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE

IEC 60601-1-2 Edition 3: 2007-03 Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements And Tests

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED [◊]

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED [◊]

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED [◊]

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

◊ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

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Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s
(To be filled in by applicant)

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TYPE OF 510(K) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE ¹

IEC 60601-2-2 Edition 5.0 2009-02 Medical Electrical Equipment - Part 2-2: Particular Requirements For The Basic Safety And Essential Performance Of High Frequency Surgical Equipment And High Frequency Surgical Accessories

Please answer the following questions

Yes No

Is this standard recognized by FDA ² ?

FDA Recognition number³ #6-228

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?

Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)?

If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?

Does this standard include acceptance criteria?

If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests?

If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard?

If yes, were deviations in accordance with the FDA supplemental information sheet (SIS)⁵?

Were deviations or adaptations made beyond what is specified in the FDA SIS?

If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard?

If yes, report these exclusions in the summary report table.

Is there an FDA guidance ⁶ that is associated with this standard?

If yes, was the guidance document followed in preparation of this 510k?

Title of guidance: _____

¹ The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

² Authority [21 U.S.C. 360d], <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm>

⁵ The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

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⁶ The online search for CDRH Guidance Documents can be found at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>

**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE

IEC 60601-2-2 Edition 5.0 2009-02 Medical Electrical Equipment - Part 2-2: Particular Requirements For The Basic Safety And Essential Performance Of High Frequency Surgical Equipment And High Frequency Surgical Accessories

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED [◊]

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED [◊]

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED [◊]

DESCRIPTION

JUSTIFICATION

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TYPE OF 510(K) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE ¹

ISO 10993-1 Fourth Edition 2009-10-15 Biological Evaluation Of Medical Devices - Part 1: Evaluation And Testing Within A Risk Management Process

Please answer the following questions

Yes No

Is this standard recognized by FDA ² ?

FDA Recognition number³ #2-179

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?

Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)?

If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?

Does this standard include acceptance criteria?

If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests?

If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard?

If yes, were deviations in accordance with the FDA supplemental information sheet (SIS)⁵?

Were deviations or adaptations made beyond what is specified in the FDA SIS?

If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard?

If yes, report these exclusions in the summary report table.

Is there an FDA guidance ⁶ that is associated with this standard?

If yes, was the guidance document followed in preparation of this 510k?

Title of guidance: ODE General Program Memorandum #G95-1 (1995)

¹ The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

² Authority [21 U.S.C. 360d], <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm>

³ <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

⁴ The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and

⁵ The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

⁶ The online search for CDRH Guidance Documents can be found at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>

**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE

ISO 10993-1 Fourth Edition 2009-10-15 Biological Evaluation Of Medical Devices - Part 1: Evaluation And Testing Within A Risk Management Process

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED [◊]

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED [◊]

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED [◊]

DESCRIPTION

JUSTIFICATION

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TYPE OF 510(K) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE ¹

AAMI ANSI ISO 10993-5:2009/(R) 2014 Biological Evaluation Of Medical Devices -- Part 5: Tests For In Vitro Cytotoxicity

Please answer the following questions

Yes No

Is this standard recognized by FDA ² ?

FDA Recognition number³ #2-153

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?

Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)?

If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?

Does this standard include acceptance criteria?

If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests?

If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard?

If yes, were deviations in accordance with the FDA supplemental information sheet (SIS)⁵?

Were deviations or adaptations made beyond what is specified in the FDA SIS?

If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard?

If yes, report these exclusions in the summary report table.

Is there an FDA guidance ⁶ that is associated with this standard?

If yes, was the guidance document followed in preparation of this 510k?

Title of guidance: _____

¹ The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

² Authority [21 U.S.C. 360d], <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm>

⁵ The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

³ <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

⁶ The online search for CDRH Guidance Documents can be found at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>

**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE

AAMI ANSI ISO 10993-5:2009/(R) 2014 Biological Evaluation Of Medical Devices -- Part 5: Tests For In Vitro Cytotoxicity

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED [◊]

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED [◊]

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED [◊]

DESCRIPTION

JUSTIFICATION

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TYPE OF 510(K) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE ¹

ISO 10993-10 Third Edition 2010-08-01 Biological Evaluation Of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization

Please answer the following questions

Yes No

Is this standard recognized by FDA ² ?

FDA Recognition number³ #2-174

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?

Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)?

If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?

Does this standard include acceptance criteria?

If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests?

If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard?

If yes, were deviations in accordance with the FDA supplemental information sheet (SIS)⁵?

Were deviations or adaptations made beyond what is specified in the FDA SIS?

If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard?

If yes, report these exclusions in the summary report table.

Is there an FDA guidance ⁶ that is associated with this standard?

If yes, was the guidance document followed in preparation of this 510k?

Title of guidance: _____

¹ The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

² Authority [21 U.S.C. 360d], <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm>

⁵ The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

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⁶ The online search for CDRH Guidance Documents can be found at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE		
STANDARD TITLE ISO 10993-10 Third Edition 2010-08-01 Biological Evaluation Of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization		
CONFORMANCE WITH STANDARD SECTIONS*		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED [◊]		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED [◊]		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED [◊]		
DESCRIPTION		
JUSTIFICATION		
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TYPE OF 510(K) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE ¹

ISO 10993-11 Second Edition 2006-08-15 Biological Evaluation Of Medical Devices Part 11: Tests For Systemic Toxicity

Please answer the following questions

Yes No

Is this standard recognized by FDA ² ?

FDA Recognition number³ #2-176

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?

Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)?

If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?

Does this standard include acceptance criteria?

If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests?

If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard?

If yes, were deviations in accordance with the FDA supplemental information sheet (SIS)⁵?

Were deviations or adaptations made beyond what is specified in the FDA SIS?

If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard?

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Is there an FDA guidance ⁶ that is associated with this standard?

If yes, was the guidance document followed in preparation of this 510k?

Title of guidance: _____

¹ The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

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² Authority [21 U.S.C. 360d], <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm>

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⁶ The online search for CDRH Guidance Documents can be found at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>

**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE

ISO 10993-11 Second Edition 2006-08-15 Biological Evaluation Of Medical Devices Part 11: Tests For Systemic Toxicity

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED [◊]

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED [◊]

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED [◊]

DESCRIPTION

JUSTIFICATION

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TYPE OF 510(K) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE ¹

ISO 10993-4:2002 Biological evaluation of medical devices -- Part 4: Selection of tests for interactions with blood

Please answer the following questions

Yes No

Is this standard recognized by FDA ² ? FDA Recognition number³ # _____Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)? Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)?

If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device? Does this standard include acceptance criteria?

If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests?

If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard? If yes, were deviations in accordance with the FDA supplemental information sheet (SIS)⁵? Were deviations or adaptations made beyond what is specified in the FDA SIS?

If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard?

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Is there an FDA guidance ⁶ that is associated with this standard? If yes, was the guidance document followed in preparation of this 510k?

Title of guidance: _____

¹ The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

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⁵ The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

³ <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

⁶ The online search for CDRH Guidance Documents can be found at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>

**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE

ISO 10993-4:2002 Biological evaluation of medical devices -- Part 4: Selection of tests for interactions with blood

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED [◊]

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED [◊]

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED [◊]

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

◊ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 1 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s
(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE ¹

ASTM F756-13, Standard Practice For Assessment Of Hemolytic Properties Of Materials. (Biocompatibility)

Please answer the following questions

Yes No

Is this standard recognized by FDA ² ?

FDA Recognition number³ #2-207

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?

Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)?

If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?

Does this standard include acceptance criteria?

If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests?

If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard?

If yes, were deviations in accordance with the FDA supplemental information sheet (SIS)⁵?

Were deviations or adaptations made beyond what is specified in the FDA SIS?

If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard?

If yes, report these exclusions in the summary report table.

Is there an FDA guidance ⁶ that is associated with this standard?

If yes, was the guidance document followed in preparation of this 510k?

Title of guidance: _____

¹ The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

² Authority [21 U.S.C. 360d], <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm>

⁵ The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

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**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE

ASTM F756-13, Standard Practice For Assessment Of Hemolytic Properties Of Materials. (Biocompatibility)

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED [◊]

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED [◊]

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED [◊]

DESCRIPTION

JUSTIFICATION

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